

TO THE HONORABLE JUDGE OF SAID COURT:

Plaintiff, the County of Leon, Texas (hereinafter “Leon County” or “County”), by and through the undersigned attorneys and on behalf of the District/County Attorney for Leon County, hereby brings suit against the named defendants, and for cause of action would respectfully show the Court and jury as follows:

I.

INTRODUCTION

1.0 Drug companies and their affiliates should never place their pursuit of profits above the public good. Unfortunately, Leon county and its citizens have found themselves to be innocent participants in the battle against opioid abuse and the crushing effects of this phenomenon on our county financially, socially, and morally. The culprits in this wrongdoing are the joined defendants, each of whom plays a meaningful role in the manufacture, distribution, and/or sale of opioid drugs in Texas and in Leon County.

1.1. Drug manufacturers have a legal duty to ensure their products are accompanied by full and accurate instructions and warnings to guide prescribing doctors and other health-care providers in making treatment decisions. These companies have a second obligation that is equally as important: the responsibility to be honest with the citizens who take their opioid drugs. They must tell the truth when marketing their drugs and ensure that their marketing claims are supported by science and medical evidence. The defendants broke these simple rules.

1.2 These defendants knew that the use of opioids had the potential to cause addiction, debilitating health maladies, and death. In spite of this knowledge, the quest for immense profits prompted the defendants to engage in a lengthy and sophisticated campaign of lies, half-truths, and deceptions to create a market for these drugs that would result in the over-prescription and

improper long-term use of these medications. The highly deceptive and unfair marketing campaign worked flawlessly and resulted in an exponential increase in opioid abuse, addiction, and death.

1.3 Unfortunately, Leon County, Texas, has found itself to be an innocent participant in the battle against opioids and their crushing effect on the Nation and Texas counties financially, socially, and morally. The culprits in this wrongdoing are the joined defendants, each of whom plays a meaningful role in the manufacture, distribution, marketing and/or sale of opioid drugs.

1.4 According to the Centers for Disease Control, opioid prescribing rates in Leon County from 2004 to 2016 were up to 39.8 per 100 persons. The insidious growth in the number of opioid drugs resulted in an unavoidable, corresponding proliferation in the volume of opioid pills available for misuse and diversion. The foreseeable outcome of the drug makers' conduct is that Leon County has been required to expend its limited resources to help those affected by this crisis and as well as funds to protect the community from the negative consequences caused by the opioid epidemic.

1.5 It is indisputable that Leon County has suffered damages in the past and will continue to suffer damages in the future.

II.

TAG-ALONG ACTION

2.0 This is a potential tag-along action and, in accordance with 28 U.S.C. 1407, may be transferred by the Joint Panel on Multi-District Litigation ("JPML"), MDL No. 2804, *In Re: National Prescription Opiate Litigation*, pending before the JPML.

III.

VENUE AND JURISDICTION

3.0 Jurisdiction is proper in the Southern District of Texas, Leon Division, pursuant to 28 U.S.C. § 1332.

3.1 This court has personal jurisdiction over the defendants because they carry on a continuous and systematic part of their general businesses within Texas, have transacted substantial business with Texas entities and residents, and have caused grave harm in Texas as a result.

3.3 The amount in controversy exceeds \$75,000, exclusive of interest and costs.

3.4 The nonresident defendants are subject to the jurisdiction of this court pursuant to the Texas long-arm statute, which authorizes jurisdiction and the exercise of jurisdiction insofar as it is consistent with federal and state due process standards. Each of the non-resident defendants does and has done business in the state. Tex. Civ. Prac. & Rem. Code Ann. § 17.042 (Vernon 2008); the cited statute extends personal jurisdiction as far as the federal constitutional requirements of due process will permit. Defendants have purposefully directed their activities toward Texas and purposefully availed themselves of the privileges and benefits of conducting activities in Texas. Specifically, the defendants committed a tort, in whole or in part, in this state, as more fully depicted in this complaint. Moreover, the defendants purposely availed themselves of the privilege of conducting activities within Texas; purposely directed their actions toward Texas and Leon County, Texas; they have substantial and continuous contacts with the State of Texas, generally, and Leon County specifically, with respect to this action, to satisfy both general and specific minimum contacts; the quality of the contacts was meaningful, with these defendants selling or making available for sell their opioid products in Texas and in Leon

County; these defendants sought a benefit, advantage, or profit by virtue of their activities in Texas. Further, the defendants committed a tort, in whole or in part, in this state, as more fully depicted in this complaint; Leon County's claims in this cause arise directly out of or result from the Defendants' activities in Texas. Defendants should reasonably anticipate being haled into court in Texas; Defendants are not being haled into court as the result of random or fortuitous conduct or as a result of the unilateral activity of any other party or third person. Exercising jurisdiction over Defendants in this matter does not offend the traditional notions of fair play and substantial justice or to constitutionally permit the court to exercise jurisdiction

3.5 Venue as to each defendant is proper in this court under 28 U.S.C. § 1391(b)(2) because a substantial part of the events and omissions giving rise to the claim occurred in the Southern District of Texas, Leon Division.

IV.

PARTIES

PLAINTIFF

4.0 Plaintiff, Leon County, is an existing county government duly formed under the laws of the State of Texas that provides a wide range of services on behalf of its residents, including, but not limited to, services for families and children, public health, public assistance, law enforcement, and social services.

DEFENDANTS

4.1 Each defendant named below manufactures, promotes, sells, markets and/or distributes opioids in Texas and Leon County.

4.2 Purdue Pharma L.P. is a limited partnership organized under the laws of Delaware with its principal place of business in Stamford, Connecticut. Purdue Pharma Inc. is a New York

corporation with its principal place of business in Stamford, Connecticut. The Purdue Frederick Company is a Delaware corporation with its principal place of business in Stamford, Connecticut. Purdue Pharmaceuticals L.P. is licensed by the Food & Drug Safety Licensing Group of the Texas Department of State Health Services (“DSHS”) as a manufacturer and/or distributor of prescription drugs in Texas (collectively “Purdue”).

4.3 Purdue manufactures, promotes, sells, and distributes opioids nationally and in Leon County, including among them OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER. OxyContin is Purdue’s best-selling opioid. Since 2009, Purdue’s annual sales of OxyContin have fluctuated between \$2.47 billion and \$2.99 billion, up four-fold from its 2006 sales of \$800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (painkillers).

4.4 Upon information and belief, Purdue is authorized to do business in Texas and conducts business in Texas and in Leon County, Texas, specifically.

4.5 Cephalon, Inc. (“Cephalon.”) is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. In 2011, Teva Ltd. acquired Cephalon. Teva Pharmaceutical Industries, Ltd., (“Teva, Ltd.”) is an Israeli company with its corporate headquarters in Petah Tikva, Israel. Teva Pharmaceuticals USA, Inc. (“Teva USA”) is a wholly-owned subsidiary of Teva Ltd., and is a Delaware corporation with its principal place of business in Pennsylvania. Teva USA acquired Cephalon in October 2011. Teva, Ltd., Teva USA, and Cephalon, Inc. (collectively “Cephalon”) work together closely to market and sell Cephalon products in the State of Texas. Teva Ltd. conducts all sales and marketing activities for Cephalon in the State of Texas through Teva USA and has done so since its October 2011 acquisition of Cephalon.

4.6 Cephalon manufactures, promotes, sells, and/or distributes opioids nationally and in Leon County, including Actiq and Fentor, for which Cephalon is identified as the drug sponsor and Teva USA is identified as the distributor.

4.7 Cephalon is engaging in business in the State of Texas and Leon County, Texas, but has not designated or maintained a resident agent for service of process.

4.8 Janssen Pharmaceuticals, Inc. (“Janssen”) is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly-owned subsidiary of Johnson & Johnson (J&J), a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. Otho-McNeil-Janssen Pharmaceuticals, Inc., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. Janssen Pharmaceutica, Inc., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. J&J is the only company that owns more than 10% of Janssen Pharmaceuticals’ stock, and corresponds with the FDA regarding Janssen’s products. Upon information and belief, J&J controls the sale and development of Janssen Pharmaceuticals’ drugs and Janssen’s profits inure to J&J’s benefit. (collectively “Janssen.”).

4.9 Janssen manufactures, promotes, sells, and/or distributes opioids nationally and in Leon County, including Duragesic, Nucynta and Nucynta ER. These opioid drugs are sold both directly by Janssen and by third party drug distributors, including Defendant Advanced Pharma, Inc., d/b/a/ Avella of Houston.

4.10 Upon information and belief, Janssen is authorized to do business in Texas and conducts business in Texas and in Leon County, Texas.

4.11 Endo Health Solutions, Inc. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. Endo Pharmaceuticals, Inc. is a wholly-owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania (collectively “Endo.”).

4.12 Endo manufactures, promotes, sells, and/or distributes opioids nationally and in Leon County, including Opana and Opana ER. Opana ER is reported to have been prescribed up to 50,000 times per day. However, on June 8, 2017, the U.S. Food and Drug Administration requested that Endo remove Opana ER from the market based on FDA’s concern that the benefits of the drug may no longer outweigh its risks.

4.13 Upon information and belief, Endo is authorized to do business in Texas and conducts business in Texas generally and in Leon County, Texas.

4.14 Abbott Laboratories is an Illinois corporation with its principal place of business in Abbott Park, Illinois. Knoll Pharmaceutical Company is a wholly-owned subsidiary of Abbott Laboratories and is a New Jersey corporation with its principal place of business in Parsippany, New Jersey (collectively “Abbott”).

4.15 Abbott currently and/or historically manufactures, promotes, sells, and/or distributes opioids nationally and in Leon County, including Vicoprofen and Dilaudid.

4.16 Upon information and belief, Abbott is authorized to do business in Texas and conducts business in Texas generally and in Leon County, Texas.

4.17 Allergan PLC is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. Actavis PLC acquired Allergan PLC in March 2015, and the combined company changed its name to Allergan PLC in January 2013. Before that, Watson

Pharmaceuticals, Inc. acquired Actavis, Inc. in October 2012, and the combined company changed its name to Allergan Finance, LLC as of October 2013. Watson Laboratories, Inc. is a Nevada corporation with its principal place of business in Corona, California, and is a wholly-owned subsidiary of Allergan PLC (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.). Actavis Pharma, Inc. (f/k/a Actavis, Inc.) is a Delaware corporation with its principal place of business in New Jersey and was formerly known as Watson Pharma, Inc. Actavis LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Each of these defendants is owned by Allergan PLC, which uses them to market and sell its drugs in Texas. Upon information and belief, Allergan PLC exercised control over these marketing and sales efforts and profits from the sale of Allergan/Actavis products ultimately inure to its benefit. (collectively “Actavis.”).

4.18 Actavis manufactures, promotes, sells, and/or distributes opioids nationally and in Leon County, including generic Oxycontin (oxycodone hydrochloride) and Dilaudid (hydromorphone hydrochloride). Allergan Sales is identified as the sponsor and/or entity responsible for the manufacture and/or distribution of the opioid medication Fiorinal with codeine (FDA NDA # 019429). Actavis acquired the rights to another opioid, Kadian (morphine sulfate, NDA # 020616), from King Pharmaceuticals, Inc. on December 30, 2008, and began marketing Kadian in 2009.

4.19 Actavis is engaging in business in the State of Texas, generally and in Leon County, Texas, but has not designated or maintained a resident agent for service of process.

4.20 Insys Therapeutics, Inc. (“Insys”) is a Delaware corporation with its principal place of business in Chandler, Arizona. Insys manufactures, promotes, sells, and/or distributes opioids nationally and in Leon County, including Subsys (fentanyl sublingual spray).

4.21 Upon information and belief, Insys is authorized to do business in Texas and maintains a facility in Round Rock, Texas.

4.22 Pfizer (“Pfizer”) is a Delaware corporation with its principal place of business in New York, New York. Pfizer manufactures, promotes, sells, and/or distributes opioids nationally and in Leon County, including Embeda. These opioid drugs are sold both directly by Pfizer or its wholly-owned subsidiary, King Pharmaceuticals, Inc. and by third party drug distributors, including defendant Advanced Pharma, Inc., d/b/a/ Avella of Houston.

4.23 Upon information and belief, Pfizer is authorized to do business in Texas. Pfizer may be served by serving its registered agent CT Corporation System, 1999 Bryan St., Ste. 900, Dallas, Texas 75201-3136.

4.24 McKesson Corporation (“McKesson”) is a Delaware corporation with its principal place of business in San Francisco, California. McKesson distributes pharmaceuticals to retail pharmacies and institutional providers across the United States, including Texas and Leon County. The drugs distributed by McKesson include powerful, addictive opioids, such as oxycodone and hydrocodone.

4.25 Upon information and belief, McKesson is authorized to do business in Texas and conducts business in Texas and in Leon County, Texas

4.26 Cardinal Health, Inc. (“Cardinal”) is an Ohio Corporation with its principal place of business in Dublin, Ohio. Cardinal distributes pharmaceuticals to retail pharmacies and institutional providers across the United States, including Texas and Leon County. The drugs distributed by Cardinal include powerful, addictive opioids, such as oxycodone and hydrocodone.

4.27 Cardinal is engaging in business in the State of Texas, and in Leon County, Texas.

4.28 Amerisource Bergen Drug Corporation (“Amerisource”) is a Delaware Corporation with its principal place of business in Chesterbrook, Pennsylvania. Amerisource distributes pharmaceuticals to retail pharmacies and institutional providers across the United States, including Texas and Leon County. The drugs distributed by Amerisource include powerful, addictive opioids, such as oxycodone and hydrocodone.

4.29 Upon information and belief, Amerisource is authorized to do business in Texas and conducts business in Texas and in Leon County, Texas.

4.30 Mallinckrodt PLC (“Mallinckrodt”) is an Irish public limited company with its corporate headquarters in Staines-Upon-Thames, Surrey, United Kingdom and maintains a U.S. headquarters in St. Louis, Missouri. Mallinckrodt distributes pharmaceuticals to retail pharmacies and institutional providers across the United States, including Texas and Leon County. The drugs distributed by McKesson include powerful, addictive opioids, such as oxycodone and hydrocodone.

4.31 Mallinckrodt also manufactures, promotes, sells, and/or distributes opioids nationally and in Leon County, including medications containing codeine, fentanyl, hydrocodone, morphine, and oxycodone. These opioid drugs are sold both directly by Mallinckrodt and by third party drug distributors, including Defendant Advanced Pharma, Inc., d/b/a/ Avella of Houston.

V.

FACTUAL ALLEGATIONS

5.0 Leon County re-alleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Petition as though fully alleged herein.

5.1. It is not possible to fairly depict the true character and scope of the calamity that has befallen Leon County and its residents due to the opioid epidemic. Even so, a brief synopsis of the foundation for this disaster and the misfortune that has resulted from the conduct of the joined defendants is instructive.

5.2 Opioids are a class of drugs that bind to opioid receptors in the brain and produce feelings of euphoria, calm, and a state of heightened relaxation. The drugs are derived from an opium compound, such as the poppy seed. Drug companies have developed synthetic, or man-made, versions of these chemical compounds. Opioids may be classified as either “recreational” or non-prescription drugs, such as heroin and opium, or prescription drugs, such as morphine, codeine, and fentanyl.¹

¹ There are dozens of opioid prescription drugs that have been marketed in the United States. Opioids have “brand” names by which they are marketed as well as “generic” or common names, which describe the chemical composition of the drug. A partial list of the brand named opioids with their generic associated name includes: Abstral (fentanyl), Actiq (fentanyl), Avinza (morphine sulfate extended-release capsules), Butrans (buprenorphine transdermal system), Demerol (meperidine [also known as isonipecaine or pethidine]), Dilaudid (hydromorphone [also known as dihydromorphinone]), Dolophine (methadone hydrochloride tablets), Duragesic (fentanyl transdermal system), Fentora (fentanyl), Hysingla (hydrocodone), Methadose (methadone), Morphabond (morphine), Nucynta ER (tapentadol extended-release oral tablets), Onsolis (fentanyl), Oramorph (morphine), Oxaydo (oxycodone), Roxanol-T (morphine), Sublimaze (fentanyl), Xtampza ER (oxycodone), Zohydro ER (hydrocodone), Anexsia (hydrocodone containing acetaminophen), Co-Gesic (hydrocodone containing acetaminophen), Embeda (morphine sulfate and naltrexone extended-release capsules), Exalgo (hydromorphone hydrochloride extended-release tablets), Hycet (hydrocodone containing acetaminophen), Hycodan (hydrocodone containing homatropine), Hydromet (hydrocodone containing homatropine), Ibudone (hydrocodone containing ibuprofen), Kadian (morphine sulfate extended-release tablets), Liquicet (hydrocodone containing acetaminophen), Lorcet (hydrocodone containing acetaminophen), Lorcet Plus (hydrocodone containing acetaminophen), Lortab (hydrocodone containing acetaminophen), Maxidone (hydrocodone containing acetaminophen), MS Contin (morphine sulfate controlled-release tablets), Norco (hydrocodone containing acetaminophen), Opana ER (oxycodone hydrochloride extended-release tablets), OxyContin (oxycodone hydrochloride controlled-release tablets), Oxycet (oxycodone containing acetaminophen), Palladone (hydromorphone hydrochloride extended-release capsules), Percocet (oxycodone containing acetaminophen), Percodan (oxycodone containing aspirin), Reprexain (hydrocodone containing ibuprofen), Rezira (hydrocodone containing pseudoephedrine), Roxicet (oxycodone containing acetaminophen), Targiniq ER (oxycodone containing naloxone), TussiCaps (hydrocodone containing chlorpheniramine), Tussionex (hydrocodone containing chlorpheniramine), Tuzistra XR (codeine containing chlorpheniramine), Tylenol #3 and #4 (codeine containing acetaminophen), Vicodin (hydrocodone containing acetaminophen), Vicodin ES (hydrocodone containing acetaminophen), Vicodin HP (hydrocodone containing acetaminophen), Vicoprofen (hydrocodone containing ibuprofen), Vituz (hydrocodone containing chlorpheniramine), Xartemis XR (oxycodone containing acetaminophen), Xodol (hydrocodone containing acetaminophen), Zolvit (hydrocodone containing acetaminophen), Zutripro (hydrocodone containing chlorpheniramine and pseudoephedrine), Zydone (hydrocodone containing acetaminophen), Fentanyl (fentanyl extended-release transdermal system), Methadone hydrochloride (methadone hydrochloride tablets, methadone hydrochloride oral solution), Morphine sulfate (morphine sulfate extended-release capsules, morphine sulfate

5.3. Opioids – both prescription and non-prescription – have been used in the United States for decades. However, the use of prescription opioids was generally restricted to a small population of patients for whom no viable treatment alternative was thought to exist.

5.4 In the 1990's, the pharmaceutical industry recognized that a potentially limitless and profitable market existed for this class of drugs. The prevailing scientific evidence and medical consensus did not support the widespread prescription and use of these drugs. In fact, controlled studies of the safety and efficacy of opioids were limited to short-term use (not longer than 90 days) and in managed settings (e.g., hospitals), where the risk of addiction and other adverse outcomes was much less significant. Indeed, the U.S. Food and Drug Administration ("FDA") has expressly recognized that there have been no long-term studies demonstrating the safety and efficacy of opioids for long-term use.²

5.5 The defendants, as well as their predecessors, affiliates, and associated entities, determined to alter the perception of opioids, first among healthcare providers and then among the consuming public. The widespread use of opioid drugs is the direct result of a concerted scheme that has evolved over the past two decades and for which each of the defendants is responsible.

5.6 The defendants and their affiliates successfully established a market for these products using nefarious means including:

- (a) creating and expanding the market for these products using baseless science, which was frequently the work of their own "product champions." This behavior included developing and disseminating seemingly truthful scientific and educational materials that misrepresented the risks and benefits of opioids for both acute pain and long-term treatment of chronic pain;

extended-release tablets), Oxymorphone hydrochloride (oxymorphone hydrochloride extended-release tablets).

² Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. Physicians for Responsible Opioid Prescribing, Re: Docet No. FDA-2012-P-0818 (Sept. 10, 2013).

- (b) deploying sales representatives who visited doctors and other prescribers and delivered misleading messages about the use of opioids, the propensity of these drugs to cause psychological or physical dependence, and the safety and efficacy of this class of medications;
- (c) enlisting either unwitting or complicit healthcare providers as their advocates and accomplices. This conduct included recruiting prescribing physicians as paid speakers, as a means of both securing those physicians' future "brand loyalty" and extending their reach to the physicians' peers. The defendants also engaged in funding, assisting, encouraging, and directing certain doctors, known as "key opinion leaders" ("KOLs"), not only to deliver scripted talks, but also to draft misleading studies, present continuing medical education programs ("CMEs") that were deceptive and lacked balance, and serve on the boards and committees of professional societies and patient advocacy groups that delivered messages and developed guidelines supporting chronic opioid therapy;
- (d) the defendants also employed the assistance of supposedly objective advocacy groups and third parties, who promoted and encouraged the widespread use of opioids. This conduct including funding, assisting, directing, and encouraging seemingly neutral and credible professional societies and patient advocacy groups (referred to hereinafter as "Front Groups") that developed educational materials and treatment guidelines that were then distributed by defendants, which urged doctors to prescribe and patients to use opioids long-term to treat chronic pain. Internal documents establish that these defendants realized that direct messaging and ads sponsored by them would be viewed more critically than messaging and ads by apparently independent third-party health care companies. Specifically, The Federation of State Medical Boards ("FSMB"), American Pain Society ("APS"), American Academy of Pain Medicine ("AAPM"), and The American Geriatrics Society ("ABS") are supposedly independent organizations concerned primarily with patient wellbeing. However, these organizations were in fact organized and funded by the defendants for the sole purpose of having seemingly independent pain organizations espousing the virtues of opioid use. One example is an organization known as the Federation of State Medical Boards. The FSMB is a trade organization that holds itself out as representing the various state medical boards in the United States. This organization was responsible for producing guidelines on the prescription of opioids. A 2004 iteration of the FSMB Guidelines proclaimed not that opioids could be appropriate in limited cases or after other treatments had failed, but that opioids were "essential" for treatment of chronic pain, including as a first prescription option. These guidelines were posted online and were available to and intended to reach Houston physicians. It came to be established, however, that the publication of Responsible Opioid Prescribing was backed largely by drug manufacturers, including Cephalon, Endo, and Purdue. Thus, the defendants succeeded in

infiltrating otherwise credible agencies and enlisting their support in the widespread, improper use of opioid medications;

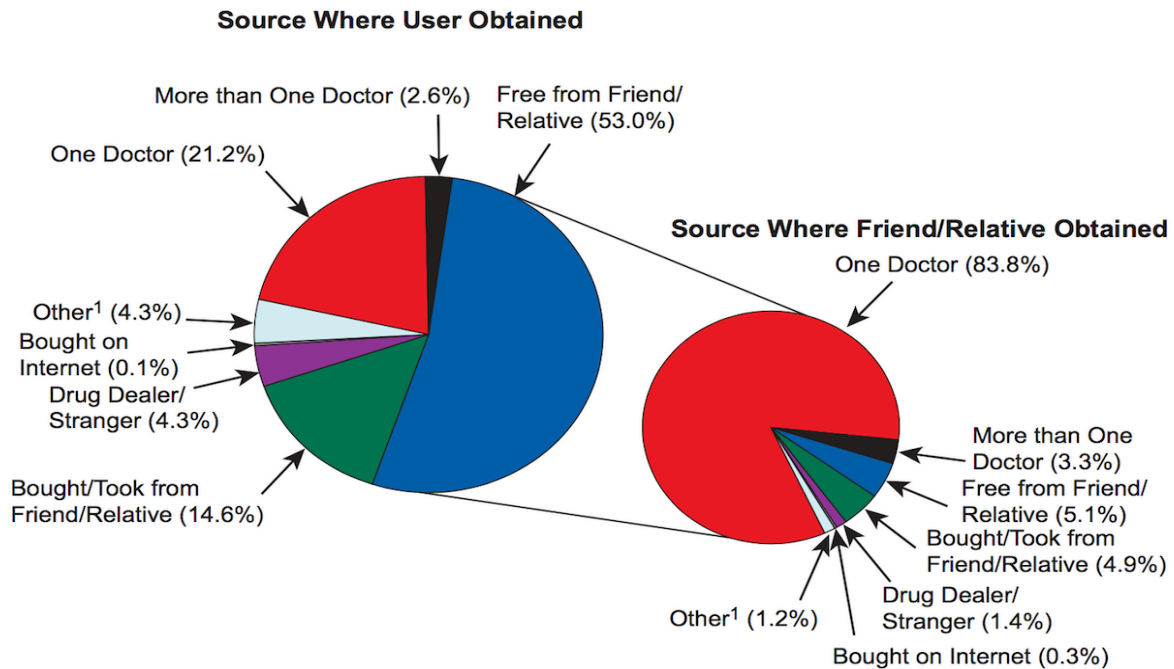
- (e) saturating the direct to consumer market with false advertising, promotions, and reassuring messages, all of which were calculated to cause and did cause consumers in Leon County to seek out these medications for improper uses; and,
- (f) aggressively defending against any challenge to their marketing schemes, undermining their detractors, allaying the concerns of regulatory bodies, and assuring the medical community and the public that the industry was looking out for the best interests of society.

5.7 In summary, these defendants seized upon the weakness of humankind to create a disaster of gargantuan proportions, the likes of which has not been seen in this country since the same conduct was perpetrated by Big Tobacco decades ago.

5.8 The conduct of the defendants was undertaken in the face of accumulating information concerning the misuse and abuse of these drugs. The defendants had access to data showing how individual doctors across the nation were prescribing opioids in general and the defendants' products specifically. The information came from sources such as IMS, a company that buys prescription data from pharmacies and resells it to drug makers for marketing purposes. Further, Defendants understood and exploited data showing that marketing to targeted healthcare providers would result in an ever-increasing market for their opioids in the public arena. This chart is an example of that phenomenon at play across the U.S.³:

³ SAMHSA, *State Estimates of Nonmedical Use of Prescription Pain Relievers*, NATION SURVEY ON DRUG USE AND HEALTH (Jan. 8, 2013) (available at <http://archive.samhsa.gov/data/2k12/NSDUH115/sr115-2526-nonmedical-use-pain-relievers.htm>).

Figure 2.16 Source Where Pain Relievers Were Obtained for Most Recent Nonmedical Use among Past Year Users Aged 12 or Older: 2012-2013



¹ The Other category includes the sources "Wrote Fake Prescription," "Stole from Doctor's Office/Clinic/Hospital/Pharmacy," and "Some Other Way."

Note: The percentages do not add to 100 percent due to rounding.

5.9 The defendants thereby successfully created and nurtured an environment in which opioid abuse was a virtual certainty. By spending millions of dollars to convince the populace that they needed and would benefit from the use of defendants' opioid drugs, these tortfeasors produced a generation of dependent drug users and abusers who believed their physical ailments were being appropriately treated by the defendants' prescription drugs. It came to pass, unfortunately, that the defendants' primary success was in producing a population of citizens whose initial use of opioids was generally legal and legitimate, but was transformed into an addiction that could be fulfilled only by the use of illegal street drugs.

5.10 The defendants also distributed or permitted the distribution of these opioids into the public arena in such quantities and through such channels that they became available for misuse in places like Leon County, Texas.⁴ In Texas, opioid medications are regulated so that it is unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by law. Each member of the chain of manufacturing and distribution has a duty to maintain vigilance regarding the potential diversion or misuse of opioid drugs. These defendants either knowingly or negligently failed in their individual and collective duties to maintain surveillance of the improper distribution and use of their opioid products.

5.11 Between 1999 and 2014 sales of prescription opioid drugs almost quadrupled in America, in large part because more of the population became addicted to these powerful drugs. Americans now consume four-fifths of the global supply.

5.12 The hardship attributable to this disaster has been disproportionately borne by the youth of Texas and of Leon County. According to recent survey findings, as of 2016, at least 5 % of Texas youth reported using opioid medications pandered by the defendants at some point during their lifetime. A shocking 2.4% of the surveyed population reported using these drugs in the past month.⁵

5.13 The abuse of prescription opioids has contributed to another unfortunate and unforeseen phenomenon: the increase in the use of “recreational” opioids, namely heroin. Across the nation, the next generation of leaders, workers, and parents have succumbed to a horrific

⁴ For example, in the area of marketing to healthcare providers involved in caesarian deliveries in the U.S. which resulted in data that such clinicians routinely prescribed excessive quantities of opioids after cesarean delivery and that patients consumed greater opioid amounts when more were prescribed. This also resulted in approximately 20 million opioid tablets introduced into communities from leftover medication after the treatment of pain after cesarean delivery each year, which are potentially available for diversion or misuse. Bateman BT, Cole NM, Maeda A, Burns SM, Houle TT, Huybrechts KF, et al. Patterns of opioid prescription and use after cesarean delivery. *Obstet Gynecol* 2017;130:29–35.

⁵ [Texas Drug Facts Among Youth 2016.](#)

increase in the risk of deaths from the use of heroin. There has been a similar, dramatic change in the use of heroin in Texas that was directly caused by the marketing and promotional efforts of the prescription opioid industry. While Texas has had some success in curbing the abuse of prescription drugs, this State has seen a prolific increase in the mortality rates of deaths due to heroin use, which is the drug most frequently used to replace opioids.

5.14 The pandemic caused by the collective actions of the defendants has also impacted the most innocent members of society – our children. Use of opioid pain relievers increased among all populations, including women of reproductive age and pregnant women. A recent report from the Centers for Disease Control and Prevention found that nearly one-third of women of reproductive age were prescribed an opioid in the previous year. Since 2000, rates of opioid use disorder among pregnant women, and the number of newborns diagnosed with opioid withdrawal after birth, known as neonatal abstinence syndrome (NAS), have increased. In 2012 alone, a with neonatal abstinence syndrome was born every 25 minutes.⁶ Not only is this condition traumatic for the child and the family, it poses a dramatic financial burden on the residents of Leon County. The costs of treating children diagnosed with NAS are exponentially higher than the costs associated with newborns not affected with NAS, some estimates as much as 400% higher. The long-term outcomes of the neonatal abstinence syndrome are difficult to predict, but likely include adverse outcomes throughout childhood, mental health and behavioral problems, as well as physical disabilities, the costs for all of which are likely to be borne by the citizens of Leon County for many years to come.

5.15 The foregoing corporate misbehavior occurred in contravention of numerous state and federal regulatory and common law commitments. Broadly speaking, the company who makes

⁶ Patrick, A Comprehensive Approach to the Opioid Epidemic, *Obstetrics & Gynecology*, VOL. 130, NO. 1, JULY 2017.

and profits from a prescription drug bears primary responsibility for marketing its drugs prudently, including maintaining drug labeling that is adequate and with ensuring that its warnings remain adequate as long as the drug is on the market.

5.16 The regulatory scheme to which these companies were subject placed the responsibility for postmarketing surveillance on the manufacturer, which was accompanied by a responsibility under Federal law to maintain their labeling and update the labeling with new safety information. Thus, the concomitant responsibilities imposed by federal and state law required these drug makers to revise their label to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug.

5.17 Defendants each owed additional duties under federal law and Texas law to monitor, detect, investigate, and report suspicious orders of prescription opiates originating from Leon County Texas.

5.18 Under the Controlled Substances Act (CSA), Congress devised a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA. See 21 U.S.C. §§ 801-971 (2006); 21 C.F.R. §§ 1300-1321 (2009).⁷ The CSA and its implementing regulation set forth strict requirements regarding registration, labeling and packaging, production quotas, drug security, and recordkeeping. *Id.* Any entity that seeks to become involved in the production or chain of

⁷ Since the passage of the Controlled Substances Act (CSA) in 1970, opioids have been regulated as controlled substances and have generally been categorized as Schedule II or Schedule III drugs. Schedule II drugs have a high potential for abuse, have a currently accepted medical use, and may lead to severe psychological or physical dependence. 21 U.S.C. § 812. Opioids are also among the medications considered so dangerous they require a Medication Guide be given directly to the patient to identify in plain language the associated risks. These regulations, codified in 21 CFR part 208, apply to certain drug and biological products that FDA determines pose a serious and significant public health concern requiring the distribution of information that is necessary to patients' safe and effective use of the drug products.

distribution of controlled substances (such as opioids) must first register with the DEA. 21 U.S.C. § 822; C.F.R. § 1301.11.

5.19 Such distributors must maintain “effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels.” 21 U.S.C. § 823(b)(1). Distributors must also “design and operate a system to disclose ... suspicious orders of controlled substances” and disclose those to the DEA. 21 C.F.R. § 1301.74. Suspicious orders include orders of unusual size, orders that deviate from normal patterns or orders of unusual frequency. Such a closed system is intended to reduce the widespread diversion of opioids out of legitimate channels into the illicit market, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control.

5.20 Under the Texas Health & Safety Code Section 481.067 (“The Texas Controlled Substances Act”), a person who is registered with the Drug Enforcement Administration to manufacture or distribute a controlled substance, such as the opioids at issue in this action, “shall keep records and maintain inventories in compliance with recordkeeping and inventory requirements of federal law and with additional rules the board or director adopts.”

5.21 The entire opioid industry failed to act responsibly to prohibit or limit illegal and inappropriate dispensing and use of these drugs. It is anticipated that the defendants will take the position that they had no or limited responsibility for misuse and abuse surveillance. This contention would be false.

5.22 Even though the US drug regulatory scheme is sometimes described as a “closed” system, the members of this industry permitted and even facilitated huge gaps in the system. As noted, opioid drug manufacturers and distributors have established and maintained “effective

controls” against the diversion of drugs from legitimate medical purposes. This is a joint and indivisible responsibility that cannot be delegated.

5.23 Both drug manufacturers and their distributors have access to information that permits them to track shipments of opioids, prescriptions by individual physicians, and dispensing activities by pharmacies.

5.24 All entities in the chain of distribution – from the drugmakers to the distributors - must alert the DEA to suspicious orders. This includes a duty to reject orders from customers if the company suspects the order is not wholly legitimate.

5.26 Drug makers also demand that each entity in the chain of distribution employ its own surveillance operations to detect inappropriate prescribing or dispensing behavior.

5.27 Industry custom, and common sense, dictate that any physician writing a high volume of opioids, or any pharmacy dispensing an inordinately high volume of these drugs, was a red flag that required action.

5.28 Unfortunately, the members of this industry – both manufacturers and distributors – shirked these responsibilities. The drug makers typically ignored blatantly improper orders and prescribing behavior and deferred to the downstream distributors. The distributors, in turn, left to the manufacturers the primary duty to ensure the propriety of shipments and prescriptions.

5.29 In an ironic twist to this scenario, the one productive use that was made of physician prescribing, tracking data was that drug makers used this information to identify doctors writing a small number of prescriptions who might be persuaded to write more.

5.30 Hence, the theory of a protected “closed” system is, in the present context, an unfortunate farce and a colossal pretext relied upon by the opioid industry to cover its collective rear end.

5.31 In this manner, the defendant ignored or blatantly violated Federal and Texas law that imposed a duty upon the manufacturers and distributors to provide effective controls and procedures to guard against theft, diversion, and improper dispensing of controlled substances. The failure of defendants to do so in Leon County resulted in opioids being delivered into Leon County at alarmingly high levels.

5.32 As shown, the drug manufacturers' concentrated marketing scheme pushed massive quantities of opioids into the public market that were distributed in concert with and by drug distributors without regard to whether they constituted suspicious orders. The impact on Leon County has been overwhelming to county resources.

5.33 The foreseeable harm from a breach of these duties was and continues to be the overuse and abuse of opiates, both prescription and recreational.

5.34 The purposeful breaches of these duties under federal law and Texas law is a direct and proximate cause of the diversion of millions of excess prescription opiates into Leon County, the misuse and diversion of these drugs, and the inevitable opioid epidemic with which your plaintiff is now confronted.

5.35 Certain of the named defendants have acknowledged the egregious and criminal nature of their business practices. For example, in May of 2007, Purdue and its top executives agreed to pay \$634.5 million to end a United States Department of Justice case. On May 19, 2007, The Purdue Frederick Company, Inc., entered a plea of guilty to Count One of an Information charging it with the felony of misbranding of OxyContin with the intent to defraud or mislead. The information to which Purdue plead guilty charged, among other things, that:

Beginning on or about December 12, 1995, and continuing until on or about June 30, 2001, certain PURDUE supervisors and employees, with the intent to defraud or mislead, marketed and promoted OxyContin as less

addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications as follows:

Trained PURDUE sales representatives and told some health care providers that it was more difficult to the oxycodone from an OxyContin tablet for the purpose of intravenous abuse, although PURDUE's own study showed that a drug abuser could extract approximately 68% of the oxycodone from a single OxyContin tablet by crushing the tablet, stirring it in water, and drawing the solution through cotton into a syringe; told PURDUE sales representatives they could tell health care providers that OxyContin potentially creates less chance for addiction than immediate-release opioids; sponsored training that taught PURDUE sales supervisors that OxyContin had fewer "peak and trough" blood level effects than immediate-release opioids resulting in less euphoria and less potential for abuse than short-acting opioids; told certain health care providers that patients could stop therapy abruptly without experiencing withdrawal symptoms and that patients who took OxyContin would not develop tolerance to the drug; and told certain health care providers that OxyContin did not cause a "buzz" or euphoria, caused less euphoria, had less addiction potential, had less abuse potential, was less likely to be diverted than immediate-release opioids, and could be used to "weed out" addicts and drug seekers.

5.36 Purdue has agreed that these facts are true, and the individual defendants, while they did not agree that they had knowledge of these things, agreed that the court could accept these facts in support of their guilty pleas.⁸ According to the Plea Agreement, "PURDUE is pleading guilty as described above because PURDUE is in fact guilty..." and the Court noted, when imposing the maximum statutory fine allowed, that "there exists aggravating circumstances of a kind, or to

⁸ Agreed Statement of Fact at para. 46, *United States of America v. The Purdue Frederick Company, et al.*, Case No. 1:07CR00029 (available at <http://i.bnet.com/blogs/purdue-agreed-facts.pdf>)

a degree, not adequately taken into consideration by the Sentencing Commission in formulating the guidelines”⁹

5.37 In 2008, Cephalon pled guilty to criminally violating the Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs and agreed to pay \$425 million, \$40 million of which was a criminal fine and \$10 million a criminal forfeiture.¹⁰ Among other things, the government was prepared to prove beyond a reasonable doubt that Cephalon engaged in a concerted plan to maximize revenue by the off-label marketing of Actiq; that over years the top levels of the company knew and approved of these efforts; that it was a highly organized and deliberate effort to maximize revenue despite legal restrictions; and that with Actiq this was particularly egregious because it is 80-100 times more potent than morphine.

5.38 On January 5, 2017, McKesson Corporation entered into an Administrative Memorandum Agreement with the DEA wherein it agreed to pay a \$150,000,000 civil penalty for violation of a 2008 MOA as well as failure to identify and report suspicious orders at its facilities in Aurora CO, Aurora IL, Delran NJ, LaCrosse WI, Lakeland FL, Landover MD, La Vista NE, Livonia MI, Methuen MA, Sante Fe Springs CA, Washington Courthouse OH and West Sacramento CA.

5.39 Janssen, Cephalon, Endo, Purdue and other opioid manufacturers and distributors engaged Key Opinion Leaders, such as Russel Portenoy, M.D., former Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York, to further promote their marketing campaign for opioids. Dr. Portenoy received research support,

⁹ *Id.*

¹⁰ Plea Agreement, *U.S. v. Cephalon, Inc.*, Criminal No. 08-598 (E.D. Penn. 2008) (available at <https://www.justice.gov/civil/file/89207/download>).

consulting fees, and honoraria. Dr. Portenoy was instrumental in the plan to open the door for the regular use of opioids to treat chronic pain.

5.40 Endo and other opioid manufacturers and/or distributors engaged in the practice of using and funding Key Opinion Leaders to hawk their opioids for chronic use, thereby placing more of its opioid into the public arena to be available for misuse.¹¹ ENDO's potent opioid, Opana ER, was removed from the market in 2017 by recommendation of the FDA because its coating/outer layer was inadequate to prevent non-medical use.

5.41 Mallinckrodt has agreed to settle claims brought by the Department of Justice that it shipped more than 500 million of its oxycodone pills into Florida between 2008 and 2012 (66% of the total in the state). Many of those pills were diverted and sold into the black market. Mallinckrodt.

5.42 On September 30, 2008, Cardinal Health entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement with the DEA related to allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities in Georgia, California and Colorado. A similar settlement was reached on December 23, 2016, as part of an administrative action taken against its Lakeland, Florida Distribution Center.

¹¹ KOL, Lynn Webster, MD, was the co-founder and Chief Medical Director of Lifetree Clinical Research, an otherwise unknown pain clinic in Salt Lake City, Utah. Dr. Webster was President in 2013, and is a current board member of AAPM, a front group that ardently supports chronic opioid therapy. He is a Senior Editor of Pain Medicine, the same journal that published ENDO special advertising supplements touting OPANA ER. Dr. Webster was the author of numerous CMEs sponsored by Cephalon, Endo and Purdue. At the same time, Dr. Webster was receiving significant funding from Drug-Maker Defendants. Endo also distributed Dr. Webster's book to doctors, which promoted the theory of "pseudoaddiction," which Dr. Webster later reversed himself, acknowledging that it obviously became too much of an excuse to give patients more medication. The State of New York settled with Endo in 2016, and reported that Endo's Vice President for Pharmacovigilance and Risk Management testified that he was not aware of any research validating the pseudoaddiction concept. Endo agreed not to continue to use the term in any training or marketing. In the Matter of Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. Assurance No.: 15-228 (available at https://ag.ny.gov/pdfs/Endo_AOD_030116-Fully_Executed.pdf)

5.43 The United States Department of Justice has recently charged that Insys bribed doctors in states around the country to get them to prescribe Insys' powerful fentanyl-based pain medication, Subsys, which was approved by the FDA only for treating cancer patients who suffered from severe nerve pain. The indictment also alleges that Insys founder, billionaire John Kapoor and the other six executives, conspired to defraud and mislead health insurance providers, who didn't want to approve payments when Subsys was prescribed for non-cancer patients.

5.44 These prosecutions and admissions of wrongdoing have come too little, too late, for a beleaguered country. On a national scale, the magnitude of the opioid crisis is incomprehensible. Most tragically, drug overdose and opioid-related deaths continue to increase in the United States. The majority of drug overdose deaths (more than six out of ten) involve an opioid. Since 1999, the number of overdose deaths involving opioids (including prescription opioids and heroin) quadrupled. From 2000 to 2015 more than half a million-people died from drug overdoses. Ninety-one Americans die every day from an opioid overdose.¹² While Texas has worked tirelessly to combat the opioid contagion, the rate of increase of drug overdose deaths has increased from 1.5 to 4.2 per 100,000 from 1999 to 2014.

5.45 The vast profits realized by defendants' wildly successful marketing schemes are reflected in the astronomical salaries for the executives who made the decisions to create, market, and exploit these prescription drugs.¹³ Hence, one clear result of the opioid epidemic has been the obscene profits enjoyed by the companies who make these drugs, as well as the salaries

¹² <https://www.cdc.gov/drugoverdose/epidemic/index.html>

¹³ While certain compensation information is not publicly available, published sources report that the CEO of Allergan (Brenton L. Saunders) was paid over \$21 million in 2016, the CEO of Johnson & Johnson (Alex Gorsky) also was paid over \$21 million, the CEO of Abbott (Miles White) was paid, \$18.8 million, and the CEO of generic drug maker Mylan (Heather Bresch) was reported to have been compensated in the amount of \$18.2 million. <http://www.equilar.com/reports/38-2-new-york-times-200-highest-paid-ceos-2016.html>

of their executive handlers.

VI.

FIRST CAUSE OF ACTION AGAINST ALL DEFENDANTS: PUBLIC NUISANCE

6.0 Leon County re-alleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

6.1 Plaintiff, Leon County, has standing to bring this claim of public nuisance against all defendants, seeking damages, injunctive relief, and abatement of such public nuisance. The Texas law of public nuisance provides various remedies to damaged or injured parties when confronted with a public nuisance created by the conduct, in whole or in part, by the defendants.

6.2 A “public” or “common” nuisance is defined in the Texas common law as a field of tort liability. As in the case of any other kind of damage, it may be inflicted by conduct intended to cause harm, by conduct which is merely negligent, or by conduct which involves an unusual hazard or risk.¹⁴ A cause of action for public nuisance may be prosecuted, therefore, when the defendants’ conduct unreasonably interferes with a right common to the public at large by affecting the public health or public order.

6.3 By engaging in the conduct referenced above, Defendants individually and collectively, created a public nuisance by unreasonably interfering with a public right and public interest. The conduct referenced herein in the creation of a public nuisance was committed by all Defendants negligently. The conduct referenced herein was abnormal, dangerous and out of place in its surroundings and constitutes a public nuisance. Such conduct constituted significant interference with the public’s health and safety, and adversely affected all or a considerable part of the Leon County community*. All such Defendants acted with intent with respect to the nature and result

¹⁴ City of Tyler v Likes, 962 S.W. 2d 48 (Tex. 1997). -

of their conduct, and it was their conscious objective and desire to engage in such conduct and to produce such result as universal addiction in exchange for their drug to reach a billion dollars in annual sales.

6.4 The character of the defendants' conduct, and their commensurate liability for same, is measured using an objective standard. Plaintiff alleges that the defendants' conduct was criminal, grossly negligent, malicious and/or negligent with regard to every aspect of their opioid business mode.

6.5 Plaintiff contends that the wrongful acts in which the defendants engaged were done in coordination with other members of this industry. Thus, this combination of drug makers and sellers are jointly responsible for the maintenance of the nuisance faced by Plaintiff, Leon County.

6.6 The conduct of the defendants has created a nuisance that, in all probability, is permanent in that it involves activity that will continue indefinitely and has resulted in injuries and damages that are constant and continuous. Such conduct is the proximate cause of Plaintiff's damages alleged herein. The harm suffered is detailed elsewhere in this Complaint, but includes the substantial costs of dealing with all aspects of the opioid epidemic including healthcare, law enforcement, and social services.

VII.

SECOND CAUSE OF ACTION AGAINST ALL DEFENDANTS: VIOLATIONS OF THE TEXAS FOOD AND DRUG ACT – FALSE ADVERTISING

7.0 Leon County re-alleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

7.1 Defendants have knowingly violated the Texas Food and Drug Act – Texas Health and Safety Code Title 6, Section 431.003, by engaging in the false advertising of their drugs in

violation of Texas law. Texas law defines “advertising” to mean “all representations disseminated in any manner or by any means, other than by labeling, for the purpose of inducing, or that are likely to induce, directly or indirectly, the purchase of food, drugs, devices, or cosmetics.”¹⁵

7.2 Defendants have a long history of representing that it is safe to treat chronic pain with long acting opioids and supplement short-acting, rapid-onset opioids for episodic pain. Yet, there is no scientific evidence supporting the safety or efficacy of opioids for long-term use. In addition, defendants communicated, through sales representatives and their sales materials that, among other things, starting patients on opioids is low risk because most patients will not become addicted and patients who are at risk of addiction could be easily identified and managed. Defendants knew these claims to be false when they were made to the public, and encouraged and permitted their sales representatives to make false charts downplaying the potential for abuse or addiction.

7.3 Because of their reliance on Defendants’ false advertising, Leon County and its residents have suffered damages.

VIII.

THIRD CAUSE OF ACTION AGAINST ALL DEFENDANTS: NEGLIGENCE

8.0 Leon County re-alleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

8.1 Each Defendant committed wrongful acts or omissions constituting negligence, all of which created a foreseeable risk to Plaintiff and its residents. Defendants’ conduct was unreasonable considering that risk.

¹⁵ Texas Health & Safety Code Sec. 431.002 (1).

8.2 In addition to the allegations as forth above, Defendants committed wrongful acts or omissions in one or more of the following ways:

- (a) Defendants misrepresented the known addictive properties of opioids.
- (b) Defendants misrepresented the known adverse health consequences of opioids.
- (c) Defendants failed to maintain systems or exercise due diligence regarding suspicious orders.
- (d) Defendants failed to detect and prevent diversion of controlled substances
- (e) Defendants failed to investigate or report suspicious orders.
- (f) Defendants distributed opioids or caused opioids to be distributed for non-medical purposes.
- (g) Defendants failed to detect and prevent opioids becoming available for misuse.
- (h) Defendants failed to ensure an adequate supply of Naloxone for the prevention of overdose deaths in the same proportion as they infused opioid prescriptions into Leon County.
- (i) Defendants failed to properly train employees, associates and representatives to identify and report over-prescribing and over-promotion of opioids.

8.3 As a proximate result, Defendants and its agents have caused Leon County to incur excessive costs to treat the opioid epidemic in its county, including but not limited to increased costs of social services, health systems, law enforcement, judicial system, treatment and treatment facilities.

8.4 Leon County and its residents are therefore entitled to damages.

IX.

**FOURTH CAUSE OF ACTION AGAINST ALL DEFENDANTS:
GROSS NEGLIGENCE**

9.0 Leon County re-alleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

9.1 Defendants marketing scheme to optimize profits by misrepresenting and falsely touting opioids as the panacea to chronic pain was done intentionally. Defendants knowingly, recklessly, and wantonly ignored the known serious dangers associated with the widespread use of opioids. When viewed objectively, Defendants' conduct involved an extreme degree of risk, considering the probability and magnitude of harm to others. Defendants were subjectively aware of and knew of this extreme risk, but nevertheless proceeded with conscious indifference to the rights, safety, and welfare of others, including Plaintiff. Plaintiff is entitled to recover punitive damages, pursuant to § 41.003(a)(2) and (3) of the Texas Civil Practice and Remedies Code and Article XVI, § 26 of the Texas Constitution.

X.

**FIFTH CAUSE OF ACTION: VIOLATIONS OF THE RACKETEER INFLUENCED
AND CORRUPT ORGANIZATIONS ACT ("RICO"), 18 U.S.C. § 1961, *ET SEQ.*
AGAINST ALL DEFENDANTS**

10.0 Leon County re-alleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

10.1 This claim is brought by the Leon County against each Defendant for actual damages, treble, damages, and equitable relief under 18 U.S.C. §1964 for violations of 18 U.S.C. §1964, *et seq.* In this matter, the evidence will establish the existence of an enterprise, as defined by law, and that the defendants each engaged in one of four specified, prohibited relationships between

the defendants and the enterprise. Thus, liability exists on behalf of the named defendants arising from their role in the enterprise.

10.2 The defendants named in this lawsuit, each and every one, are guilty of violations of the Racketeer Influenced and Corrupt Organization Act, commonly known as the RICO statute. The alleged conduct violated 18 U.S.C. § 1962 (c) or (d).

10.3 Section 1962(c) makes it “unlawful for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise’s affairs through a pattern of racketeering activity . . .” 18 U.S.C. §1962(c).

10.4 Each Defendant conducted the affairs of an enterprise through a pattern of racketeering activity, in violation of 18 U.S.C. §1962(c) and §1962(d). While the roles of the defendants varied, each engaged in conduct and/or participated in the conduct of the enterprise by having some part in directing the affairs of the enterprise, or otherwise playing a role in the operation or management of the enterprise, or being associated with those who exert control over the enterprise, all to a sufficient degree necessary to give rise to liability under the relevant statute.

10.5 Each Defendant herein constituted an Enterprise for purposes of 18 U.S.C. § 1961(3) that created and maintained systematic links for a common purpose: to over-promote, over-sell and over-distribute drugs, specifically opioids, that have little or no demonstrated efficacy for the pain they are purported to treat in the majority of persons that obtain prescriptions for them or to be made available for misuse.

10.6 To accomplish this purpose, the Enterprise engaged in a sophisticated, well-developed, and fraudulent marketing scheme designed to increase the prescription rate for the sale and

distribution of Defendants' opioids and popularize the misunderstanding that opioids are effective for chronic pain and the risk of addiction is low ("the Scheme").

10.7 At all relevant times, each Defendants was aware of the Enterprise's conduct, was a knowing and willing participant in that conduct, and reaped profits from that conduct in the form of increased sales, distributions, and prescriptions of opioids. In fact, Front Groups and KOLs received direct payments from Manufacturer Defendants in exchange their role in the Enterprise, and to advance the Enterprises' fraudulent marketing scheme whereas Distributor Defendants received kick-backs from Manufacturing Defendants if they reached particular monthly goals.

10.8 The Enterprise engaged in, and its activities affected, interstate and foreign commerce because it involved commercial activities across state boundaries, including but not limited to: (1) marketing, promotion, and advertisement of Defendants' opioid medicines; (2) advocacy at the state and federal level for change in the law governing the use, prescription, and distribution of Defendants' opioids; (3) issuing prescriptions and prescription guidelines for Defendants' opioids; and (4) issuing fees, bills, and statements demanding payment for prescriptions of Defendants' opioids.

10.9 The persons engaged in the Enterprise are systematically linked through contractual relationships, financial ties, and continuing coordination of activities, as spearheaded by the defendants who manufactured these drugs. The misconduct of the defendants arose from a common goal of this RICO enterprise, which was to create and grow a market and off-market for opioid prescription drugs even though the proffered uses were not supported by valid scientific or medical evidence.

10.10 The Enterprise functioned as a continuing unit for the purposes of executing the Scheme and when issues arose during the Scheme, each member of the Enterprise agreed to take actions

to hide the Scheme and the existence of the Enterprise. Each of these acts were related to each other and had continuity, in that the activity or threat of such activity was ongoing and the defendants' efforts to over-promote opioid drugs was constant.

10.11 Each Defendant participated in the operation and management of the Enterprise by directing its affairs as described herein. The prohibited conduct in which the defendants engaged had the same purpose – over-promoting opioid prescription drugs and profiting from such; the same results – creating a robust market for these drugs across the county and in Leon County; the same victims – the citizens of the United States in general and Leon County in particular; and the same methods of commission – pursuing an intricate, pervasive marketing plan directed at both healthcare providers and the public to convince them to seek out, prescribe, and use these drugs.

10.12 While Defendants participated in, and are members of, the Enterprise, they have an existence separate from the Enterprise, including distinct legal statuses, affairs, offices and roles, officers, directors, employees, and individual personhood.

10.13 Defendants, singularly or in combination with another, orchestrated the affairs of the Enterprise and exerted substantial control over the Enterprise by, at least: (1) making misleading statements about the purported benefits, efficacy, and risks of opioids to doctors, patients, the public, and others, in the form of telephonic and electronic communications, CME programs, medical journals, advertisements, and websites; (2) employing sales representatives or detailers to over-promote the use of opioid medications; (3) purchasing and utilizing sophisticated marketing data (e.g., IMS data) to coordinate and refine the Scheme; (4) employing doctors to serve as speakers at or attend all-expense paid trips to programs emphasizing the benefits of prescribing opioid medications; (5) funding, controlling, and operating the Front Groups to target doctors, patients, and lawmakers and provide a veneer of legitimacy to the Manufacturer

Defendants' Scheme; (6) retaining KOLs to promote the use of their opioid medicines and (7) concealing the true nature of their relationship with the other members of the Enterprise, including the Front Groups and the KOLs.

10.14 To carry out, or attempt to carry out, the scheme to defraud, the members of the Enterprise, each of whom is a person associated-in-fact with the Enterprise, did knowingly conduct or participate, directly or indirectly, in the affairs of the Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. §§1961(1), 1961(5) and 1962(c), and employed the use of the mail and wire facilities, in violation of 18 U.S.C. §1341 (mail fraud) and §1343 (wire fraud).

10.15 Specifically, the members of the Enterprise have committed, conspired to commit, and/or aided and abetted in the commission of, at least two predicate acts of racketeering activity (i.e., violations of 18 U.S.C. §§1341 and 1343), within the past ten years.

10.16 The Enterprise's predicate acts of racketeering (18 U.S.C. §1961(1)) include, but are not limited to:

- (a) Mail Fraud: The members of the Enterprise violated 18 U.S.C. §1341 by sending or receiving, or by causing to be sent and/or received, fraudulent materials via U.S. mail or commercial interstate carriers for the purpose of selling drugs, specifically opioids, that have little or no demonstrated efficacy for the pain they are purported to treat in the majority of persons prescribed them.
- (b) Wire Fraud: The members of the Enterprise violated 18 U.S.C. §1343 by transmitting and/or receiving, or by causing to be transmitted and/or received,

fraudulent materials by wire for the purpose of selling drugs, specifically opioids, that have little or no demonstrated efficacy for the pain they are purported to treat in the majority of persons prescribed them.

10.17 These communications were integral to the commission of the torts and wrongs alleged herein, they constituted a pattern in that they have the same or similar purposes, results, participants, victims, or methods of commission, or otherwise are interrelated by distinguishing characteristics and are not isolated events, and each such communication is a violation of federal and/or state law.

10.18 The mail and wire transmissions were made in furtherance of Defendants' Scheme and common course of conduct designed to sell drugs that have little or no demonstrated efficacy for chronic pain; increase the prescription rate for opioids; and popularize the misunderstanding that the risk of addiction is low when using opioids.

10.19 The members of the Enterprise aided and abetted others in violating the law. To achieve their common goals, the members of the Enterprise hid from Leon County and its residents: (1) the fraudulent nature of Defendants' marketing scheme; (2) the fraudulent nature of statements made by Defendants and on behalf of Defendants regarding the efficacy of and risk of addiction associated with Defendants' opioids; and (3) the true nature of the relationship between the members of the Enterprise.

10.20 Plaintiff also alleges that it was injured by a conspiracy to violate Section 1962(c), as more fully elucidated in this complaint, as permitted by Section 1962(d). The defendants consciously agreed to work together to build the market for opioids, pursuant to which they committed numerous acts of wire and/or mail fraud, all of which was part of a pattern of

racketeering activity. The other named defendants consciously participated in and/or supported this conspiracy.

10.21 Defendants and each member of the Enterprise, with knowledge and intent, agreed to the overall objectives of the Scheme and participated in the common course of conduct. Indeed, for the conspiracy to succeed, each of the members of the Enterprise and their co-conspirators agreed to conceal their fraudulent scheme.

10.22 The members of the Enterprise knew, and intended that, Leon County and its residents would rely on the material misrepresentations and omissions made by them and suffer damages and a result.

10.23 Each of the defendants, to a greater or lesser extent, engaged in wrongful and illegal conduct starting no later than the date of introduction of their various opioid drugs products on the US market and continuing thereafter to the present. The pattern of racketeering activity described herein is currently ongoing and open-ended, and threatens to continue indefinitely unless this court enjoins the racketeering activity.

10.24 Plaintiffs allege that the coordinated behavior of the named defendants constituted an enterprise and/or an “association in fact” enterprise, as that term is known under the statute and the case law interpreting the same. This association in fact is not named as a party, but it is an independent entity that maintains a formal or informal structure consisting of actors, including the named defendants and others to potentially be named.

10.25 This “association in fact” was an enterprise that engaged in a pattern of wrongdoing. The predicate acts, including wire and mail fraud, were a regular way of doing business in interstate commerce for this RICO enterprise.

10.26 There has been no criminal conviction or charges arising from these events thus far in

Leon County, Texas. Nonetheless, Texas law also prohibits the types of conduct described in this petition. Moreover, certain of the defendants have either been charged with or admitted to violations of civil or criminal statutes, as described in this complaint.

10.27 Therefore, whether alleged under the provisions of state or federal law, plaintiffs would show that the named defendants have, individually and/or jointly, engaged in a pattern of activity that violates the law; or conspired to engage in such behavior; and such behavior took place across state lines. The primary objective of the enterprise was to sell and profit from the sale of opioid drugs. Hence, defendants are accountable for all forms of relief available under federal or state law.

10.28 There is a direct causal relationship between the alleged injuries and the violations of the RICO statute in that the defendants' marketing, promotional, and business activities arose from predicate acts that actually did serve to achieve the successful sale of the defendants' opioid prescription drugs. It will be shown that, as a result of the conduct summarized above, Leon County suffered dire financial consequences, with this outcome being completely foreseeable to the defendants and, in fact, a calculated consequence of the actions of the defendants. Some of the damages that were sustained are described elsewhere in this pleading.

10.29 As a result of Defendants' racketeering activity, Leon County has been injured in their business and/or property in multiple ways, including but not limited to increased health care costs, increased human services costs, costs related to dealing with opioid-related crimes and emergencies, and other public safety costs.

10.30 Defendants' violations of 18 U.S.C. §1962(c) and (d) have directly and proximately caused injuries and damages to Leon County and the public who are entitled to bring this action

for three times its actual damages, as well as injunctive/equitable relief, costs, and reasonable attorney's fees pursuant to 18 U.S.C. §1964(c).

XI.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully prays that Defendants be cited to appear and answer herein, that this cause be set down for trial before a jury, and that Plaintiff recovers judgment of and from Defendants for economic, noneconomic and punitive damages as necessary to address Leon County's claims for relief and such sums as necessary to eliminate the hazard to public health and safety and to abate, or cause to be abated, the public nuisance caused by the opioid epidemic, actual damages, as well as injunctive/equitable relief, costs, and reasonable attorney's fees pursuant to 18 U.S.C. §1964(c), as well as any other damages as may be available at law or in equity.

Dated November 14, 2017.

Respectfully submitted,

Leon County, Texas

By: /s/ James Caleb Henson
James Caleb Henson
Texas Bar. No. 24091457
County Attorney
Leon County
130 E. St. Mary
P.O. Box 429
Centerville, Texas 75833
(903) 536-7044 (Telephone)
(903) 536-7044 (Facsimile)

/s/ Mikal C. Watts

Mikal C. Watts
TX State Bar No. 20981820
Federal Bar No. 12419
Shelly A. Sanford
TX State Bar No. 00784904
Federal Bar No. 19105
WATTS GUERRA LLP
811 Barton Springs Rd., Ste. 725
Austin, TX 78704
Telephone: (512) 479-0500
Facsimile: (512) 479-0502
Email: ssanford@wattsguerra.com
mcwatts@wattsguerra.com

Alicia O'Neill
O'NEILL LAW
601 Pennsylvania Ave.NW
Suite 900
Washington, DC 20004
Telephone: (202) 629-0535
Email: aoneill@aoneill-law.com

Mike Gallagher
THE GALLAGHER LAW FIRM
2905 Sackett Street
Houston, Texas 77098
Telephone: (713) 222-8080
Facsimile: (713) 222-0066
Email: mike@gld-law.com

Tommy Fibich
FIBICH, LEEBRON, COPELAND & BRIGGS
1150 Bissonnet Street
Houston, Texas 77005
Telephone: (713) 751-0025
Facsimile: (713) 751-0030
Email: tfibich@fibichlaw.com

**COUNSEL FOR PLAINTIFF
LEON COUNTY, TEXAS**